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VB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/559,764 | 04/27/00 | FLODGAARD H | 5694.200-US |

HM22/1018

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| EXAMINER | |
|---|---|
| ROARK, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | 6 |

**DATE MAILED:** 10/18/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/559,764 | FLODGAARD ET AL. | |
| | Examiner | Art Unit | |
| | Jessica H. Roark | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-42 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

### *Restriction election*

1. The following is noted:

Groups encompass methods of treatment and kits which employ separate and distinct products (aprotinin versus antibodies to HBP. Aprotinin and antibodies to HBP differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other.

Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 drawn to a method of preventing or treating a disorder resulting from bradykinin release using an HBP antagonist *wherein the antagonist is aprotinin*, classified in Class 514, subclass 2.

II. Claims 1-8, and 12-14, drawn to a method of preventing or treating a disorder resulting from bradykinin release using an HBP antagonist *wherein the antagonist is an antibody*, classified in Class 424, subclass 139.1.

III. Claims 15-28, drawn to a method of identifying an HBP antagonist, classified in Class 435, subclass 7.1.

IV. Claims 29-31 and 38-41, drawn to a method of determining if a mammals produces HBP, classified in Class 435, subclass 7.1; and Class 436, subclass 63.

V. Claims 32-37, drawn to a kit comprising an HBP antagonist wherein the antagonist is *aprotinin*, classified in Class 435, subclass 810; and Class 530, subclass 380.

VI. Claims 32-37 and 42, drawn to a kit comprising an HBP antagonist wherein the antagonist is *an antibody*, classified in Class 435, subclass 810; and Class 530, subclass 387.9.

3. Inventions I-IV are different methods/methods of use. These inventions require different ingredients and process steps to accomplish different endpoints. Therefore, they are patentably distinct.

4. Inventions V-VI are different products. Aprotinin and antibodies to HBP are distinct because their modes of action and/or structures are different. Therefore, they are patentably distinct.

5. Inventions (V and I) and (VI and II), respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, aprotinin can be used as an immunogen to produce antibodies as well as in the treatment methods claimed; the antibody to HBP can be used to purify HBP as for the treatment method claimed. Therefore they are patentably distinct.

6. Inventions (I/II and III) are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

*species election*

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions **I and II**: wherein the disorder is:

A) systemic inflammatory response syndrome,
B) ischemia reperfusion,
C) anaphylaxis,
D) allograft rejection, or
E) adult respiratory distress syndrome.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. A telephone call was made to Valeta Gregg on 10/3/00 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
October 12, 2000

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PRIMARY EXAMINER
TECH CENTER 1600
10/14/01